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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/538,882	OSHIMA ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10, 12-17 and 19-30* is/are rejected.

7)☒ Claim(s) *11 and 18* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on June 7, 2006 is acknowledged. Claims 1-3 and newly added claims 4-30 are pending and under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objections/Rejections Withdrawn

1. In view of applicants' amendment the objection of the disclosure for informalities (misspelled words in the specification) on page 2, paragraph 3 is withdrawn.

2. In view of applicants' amendment the objection for the use of multiple trademarks on page 3, paragraph 4 is withdrawn.

3. In view of applicants' amendment the objection to claims 1-3 for informalities (misspelled words in the claims) on page 3, paragraph 5 is withdrawn.

4. In view of applicants' amendment the objection to claim 2 for being of improper dependent form on page 3, paragraph 6 is withdrawn.

5. In view of applicants' amendment the rejection of claims 1-3 under 35 U.S.C. 112, second paragraph as being rendered vague and indefinite by the use of the terms

"as an effect component", "an effective dosage" and "components of the cells" is withdrawn.

Priority

6. The examiner would like to reiterate that should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

Rejections Maintained

7. Claims 1-3 and newly added claims 4-8, 12-15, 20-22, 24, 26-28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Masunari et al (Efficacy of vaccination for coldwater disease in Ayu *Plecoglossus altivelis,* Bulletin of the Fisheries Experiment Station, Okayama Prefecture, 2001; 16: 49-57 (translation pages 1-14)) is for the reasons set forth in the previous office action on pages 4-5, paragraphs 8-9 in the rejection of claims 1-3.

The rejection is on the grounds that Masunari et al discloses a vaccine comprising formalin-killed *Flavobacterium psychrophilum* cells. Moreover, Masunari et al discloses that the vaccine is to be used for the prevention of the cold-water disease in Ayu (fish) (page 4, paragraph 3; title). The vaccine of the prior art is the same of that which is claimed. Inherently, the inactivated cells components comprise cell membrane components, vesicles, and/or secretary products.

It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. the ability to prevent cold water disease in fish. The purification, isolation or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re* Thorpe, 227 USPTO 964 (CAFC 1985); *In re* Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); *In re* Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or

practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Moreover, Masunari et al discloses a method for preventing the cold-water disease in fish, comprising administering 0.05 ml of inactivated cells of *Flavobacterium psychrophilum* to fish (page 4, paragraph 4). The method of the prior art is the same of that which is claimed. Limitations such as an effective dosage range are being viewed as limitations of optimizing experimental parameters.

Applicant argues that 1) Masunari et al does not disclose inactivation of a logarithmic growth phase culture and 2) in view of the results shown in the examples the present application the claimed invention would not be obvious in view of these references.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to a pharmaceutically administrable composition comprising inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant. Subsequent claims are drawn to a method for preventing the cold-water disease in fish, comprising administering an effective dosage of the composition according to claim 1 to a fish in need thereof to thus prevent cold-water disease.

With regard to Point 1, logarithmic phase is defined as the phase where binary fission occurs and the rate of increase in cell number is multiplication function of cell number. The culture of Masunari et al is in logarithmic phase because the cells are increased in cell number and is a multiplication function of the cell number.

Moreover, Applicant has not provided via a side-by-side comparison to the contrary that there is a material difference between the claimed invention and that of the art. It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the

same or similar functional characteristics, i.e. cells of *Flavobacterium psychrophilum* for the prevention of cold-water disease in fish. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re* Thorpe, 227 USPTO 964 (CAFC 1985); *In re* Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); *In re* Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

With regard to Point 2, applicants' argument is not germane because a rejection under 35 U.S.C. 102 is based on anticipation not obviousness.

8. Claims 1-3 and newly added claims 4-8, 12-15, 20-22, 24, 26-28 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by Rahman et al (The outer membrane fractions of *Flavobacterium psychrophilum* induces protective immunity in rainbow trout and ayu, Fish and Shellfish Immunology, 2002; 12: 169-79) for the

reasons set forth in the previous office action on pages 5-6, paragraphs 10-11 in the rejection of claims 1-3.

The rejection is on the grounds that Rahman et al discloses a *Flavobacterium psychrophilum* vaccine based on the antigenic outer membrane fraction of the cell (abstract). Rahman et al discloses that the bacterin was inactivated with formalin (page 170, preparation of the vaccines). Lastly, Rahman et al discloses that the supernatant was centrifuged and re-suspended in distilled water (page 171, 1st full paragraph). The vaccine of the prior art is the same of that which is claimed.

It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. the ability to prevent cold water disease in fish. The purification, isolation or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re* Thorpe, 227 USPTO 964 (CAFC 1985); *In re* Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); *In re* Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Moreover, Rahman et al discloses a method for preventing cold-water disease in rainbow trout and ayu (abstract). Moreover, Rahman et al discloses that the fish were immunized with a *Flavobacterium psychrophilum* vaccine based on the antigenic outer membrane fraction (abstract, page 171-vaccination). The method of the prior art is the same of that which is claimed. Limitations such as an effective dosage range are being viewed as limitations of optimizing experimental parameters.

Applicant argues that 1) Rahman et al does not disclose inactivation of a logarithmic growth phase culture and 2) in view of the results shown in the examples the present application the claimed invention would not be obvious in view of these references.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to a pharmaceutically administrable composition comprising inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant. Subsequent claims are drawn to a method for preventing the cold-water disease in fish, comprising

administering an effective dosage of the composition according to claim 1 to a fish in need thereof to thus prevent cold-water disease.

With regard to Point 1, Rahman et al discloses that cultures were grown and harvested by centrifugation while still in logarithmic growth phase (page 173; culture conditions in broth medium).

With regard to Point 2, applicants' argument is not germane because a rejection under 35 U.S.C. 102 is based on anticipation not obviousness.

9. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Kondo et al (Changes in the cell structure of *Flavobacterium psychrophilum* with length of culture, Microbiol. Immunol., 2001; 45(12): 813-18) is maintained for the reasons set forth in the previous office action on page 7, paragraph 12.

The rejection is on the grounds that Kondo et al discloses a 36-hour culture that comprises *Flavobacterium psychrophilum.* Kondo et al discloses that this culture had the highest mortality of immersion infection, which indicates that the bacterium at the logarithmic culture phase has a high virulence (page 817, 1st column). The vaccine of the prior art is the same of that which is claimed. Claim limitations such as "vaccine" and "against the cold-water disease in fish " are being viewed as limitations of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the art. See *In re Casey,* 152 USPQ 235 (CCPA 1967) and *In re Otto,* 136 USPQ 458, 458.

Applicant argues that 1) claims 1 and 2 have been rewritten as compositions that contain additional components in addition to the logarithmic growth phase culture or components thereof.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to a pharmaceutically administrable composition comprising inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant.

With regard to Point 1, Applicant has not provided via a side-by-side comparison to the contrary that there is a material difference between the claimed invention and that of the art. It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. cells of *Flavobacterium psychrophilum* for the prevention of cold-water disease in fish. The purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re* Thorpe, 227 USPTO 964 (CAFC 1985); *In re* Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); *In re* Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

10. Claims 1-3 and newly added claims 4-9, 12-16, 20-22, 24, 26-28 and 30 are reject under 35 U.S.C. 102(a) as being anticipated by LaFrentz et al for the reasons set forth in the previous office action on pages 7-8, paragraphs 13-14 in the rejection of claims 1-3.

The rejection is on the grounds that LaFrentz et al discloses a vaccine that comprises killed *Flavobacterium psychrophilum* cells, which were effective against bacterial coldwater disease in fish (page 705 &710; 1st column). LaFrentz et al discloses that *Flavobacterium psychrophilum* cells were killed by formalin and harvested by centrifugation. Moreover, LaFrentz discloses that the cells were re-suspended in physiological saline (page 705, 1st column, 1st paragraph). Inherently, the inactivated cells components comprise cell membrane components, vesicles, and/or secretary products.

It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. the ability to prevent cold water disease in fish. The purification, isolation or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re* Thorpe, 227 USPTO 964 (CAFC 1985); *In re* Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); *In re* Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

Moreover, LaFrentz et al discloses a method for preventing cold-water disease in rainbow trout by administering a vaccine comprising killed *Flavobacterium psychrophilum* cells (pages 704- bacterial culture; 705-fish immunizations). Additionally, LaFrentz discloses that the fish were immunized by immersion. Bath solutions were prepared by suspending formalin-killed *Flavobacterium psychrophilum* cells in water. For rainbow trout immunizations, an additional immersion was included (page 705, immersion delivery). The method of the prior art is the same of that which is claimed. Limitations such as an effective dosage range are being viewed as limitations of optimizing experimental parameters.

Applicant argues that 1) LaFrentz et al does not disclose inactivation of a logarithmic growth phase culture and 2) in view of the results shown in the examples the present application the claimed invention would not be obvious in view of these references.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to a pharmaceutically administrable composition comprising inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth

phase and at least one pharmaceutically acceptable carrier or adjuvant. Subsequent claims are drawn to a method for preventing the cold-water disease in fish, comprising administering an effective dosage of the composition according to claim 1 to a fish in need thereof to thus prevent cold-water disease.

With regard to Point 1, logarithmic phase is defined as the phase where binary fission occurs and the rate of increase in cell number is multiplication function of cell number. The culture of LaFrentz et al is in logarithmic phase because the cells are increased in cell number and is a multiplication function of the cell number.

With regard to Point 2, applicants' argument is not germane because a rejection under 35 U.S.C. 102 is based on anticipation not obviousness.

New Grounds of Rejection Necessitated by Amendment

Claim Rejections - 35 USC § 112

11. Claims 12-13 recites the limitation "wherein said *Flavobacterium psychrophilum* in a logarithmic growth phase are isolated from a growth culture by centrifugation or filtration" in lines 1-3 and "wherein said *Flavobacterium psychrophilum* in a logarithmic growth phase are inactivated" in lines 1-2. However, claim 2 is drawn to components of inactivated cells of *Flavobacterium psychrophilum.* There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. Claims 1-30 are rejected under 35 U.S.C. 102(a) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kondo et al (Efficacy of oral vaccine against bacterial coldwater disease in ayu *Plecoglossus altivelis*, Diseases of Aquatic Organisms, August 4, 2003; 55(3): 261-64).

The instant invention is drawn to a pharmaceutically administrable composition comprising inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant. Subsequent claims are drawn to a method for preventing the cold-water disease in fish, comprising administering an effective dosage of the composition according to claim 1 to a fish in need thereof to thus prevent cold-water disease.

Kondo et al discloses a method of preventing coldwater disease in ayu comprising orally administering formalin-killed cells of *Flavobacterium psychrophilum* in a logarithmic growth phase (abstract; 1st column-page 261). Moreover, Kondo et al

discloses that the formalin-killed bacteria cells were harvested by centrifugation. Fish were immunized by feeding dry pellets mixed with the vaccine at a rate of 0.1 to 0.2 g FKC per kg fish body weight per day, every day for two weeks (Fish and vaccination, page 261). The method and composition of the prior art are the same or equivalent to the claimed method and composition. Inherently, the inactivated cells comprise cell membrane components, vesicles, and secretary products.

With regard to claims 8, 9, 15 and 16 the examiner is viewing the water which will be present to assist in the administration of the dry pellets mixed with the vaccine as a liquid carrier.

It should be remembered that the products of the prior art reference appear to be the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics, i.e. the ability to prevent cold water disease in fish. The purification, isolation or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when the process does not change properties of the product in an unexpected manner. See *In re* Thorpe, 227 USPTO 964 (CAFC 1985); *In re* Marosi, 218 USPTO 289, 29222-293 (CAFC 1983); *In re* Brown, 173 USPTO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, great stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in

the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts to applicants product in order to overcome the aspect of the product's purity.

In the alternative, Kondo et al does not specifically teach administering a composition comprising inactivated cells of *Flavobacterium psychrophilum* in a logarithmic growth phase and at least one pharmaceutically acceptable carrier or adjuvant to an adult fish or inactivation by heat treatment or talc as a solid carrier.

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Kondo et al by administering the above-mentioned compositions to an adult fish for economical reasons and for overall protection of fish from a cold-water disease. Additionally, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Kondo et al by inactivating the cells by heat treatment because heat treatment is an obvious alternative to formalin and is well known in the art. Lastly, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Kondo et al by using talc as a solid carrier because talc is an obvious type of solid carrier and is commonly used in pharmaceutical compositions. One would have had a reasonable expectation, barring evidence to the contrary, that the method and the composition as discloses above would be effective for preventing the cold-water disease in fish.

Conclusion

13. No claim is allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 7-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's acting supervisor, Mark Navarro can be reached on 571-272-0861. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/ZJT/
9/21/06

ROBERT A. ZEMAN
PRIMARY EXAMINER